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Dated: August 27, 2009

Signature: Meaghan L. Richmond/
Electronic Signature for Meaghan L. Richmond, Ph.D.

Docket No.: 117728-22201
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:

Mark L. Nelson *et al.*

Patent No.: 7553828 B2

Confirmation No.: 1902

Issued: June 30, 2009

Art Unit: 1617

For: 9-AMINOMETHYL SUBSTITUTED
MINOCYCLINE COMPOUNDS

Examiner: S.N. Qazi

MS Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR §1.702(b)(2)

Dear Sir:

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration under 37 CFR §1.705(d)” for the above-identified patent. In view of the following, it is respectfully requested that Patentees be granted a minimum patent term adjustment of **703 days**.
2. The patent term adjustment on the “Determination of Patent Term Adjustment under 35 U.S.C. §1.54(b)” as shown on the face of the issued patent is 358 days. The determination of 358 days is in error in that, pursuant to 35 U.S.C. §1.54(b), the Office failed to issue a patent within three years of the actual filing date of the above identified application in accordance with 37 CFR §1.703(b).
3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to

the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704 (the period of Patentee Delay). In the above-identified patent, Patentees are entitled to a period of examination delay equal to the sum of the periods of delay under § 1.702(b) and §§ 1.703(a)(1) and (a)(2) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to 37 CFR § 1.703(a)(1)

In accordance with 37 CFR § 1.703(a)(1), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. § 132 not later than 14 months after the actual filing date (hereinafter “the 14 Month Delay”). Specifically, Patentees are entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after the date of which the above-identified patent was filed under 35 U.S.C. § 111(a), *i.e.*, February 24, 2004, and ending on the date of mailing of an action under 35 U.S.C. § 132, *i.e.*, a Restriction Requirement mailed from the Office on October 11, 2006. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 535 days, which is in agreement with the period calculated by the Office on the Patent Term Adjustment History, enclosed herein as Appendix A.

(ii) “Four Month Delay” Pursuant to 37 CFR § 1.703(a)(2)

In accordance with 37 CFR § 1.703(a)(2), Patentees are entitled to a period of delay due to the failure by the Office to mail an action under 35 U.S.C. § 132 no later than four months after a reply under 35 U.S.C. § 132 was filed (hereinafter “the Four Month Delay”). In particular, Patentees are entitled to a period of patent term adjustment beginning on the day after the date that is four months after the date a reply under 37 CFR § 1.111 was filed, *i.e.*, June 27, 2008, and ending on the date of mailing of a Non-final Office Action under 35 U.S.C. § 132, *i.e.*, December 1, 2008. Accordingly, the period of patent term adjustment due to the Four Month Delay by the Office is 35 days, which is in agreement with the period calculated by the Office on the Patent Term Adjustment History (Appendix A).

(iii) “Three Years Delay” Pursuant to 37 CFR § 1.702(b)

Pursuant to 37 CFR § 1.702(b), Patentees are entitled to a period of delay due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. § 111(a) (hereinafter “the Three Year Date”). Applicants note that the

Office failed to comply with this requirement, and therefore, Patentees have calculated a maximum of Three Years Delay of 856 days based on the period of time beginning on the day after the date that is three years after the date on which the above-identified patent was filed under 35 U.S.C. § 111(a), *i.e.*, February 25, 2007, and the date that the patent issued, *i.e.*, June 30, 2009.

a) Exclusion for Continued Examination

As set forth in 37 CFR § 1.703(b)(1), the Three Years Delay requirement does not include the period consumed by continued examination of the application under 35 U.S.C. § 132(b) beginning on the date on which a request for continued examination of the application under 35 U.S.C. § 132(b) was filed and ending on the date the patent was issued. Patentees note that a request for continued examination under 35 U.S.C. § 132(b) was filed on February 26, 2008, and therefore, 491 days of patent term is excluded from this calculation *i.e.*, the days between the date of the filing of the request for continued examination and the date the patent was issued, *i.e.*, June 30, 2009.

b) Exclusion for Notice of Appeal

As set forth in 37 CFR § 1.703(b)(4), the Three Years Delay requirement does not include the period of appellate review by the BPAI or a Federal court, beginning on the date on which a notice of appeal to the BPAI was filed under 35 U.S.C. § 134 and 37 CFR § 41.31 and ending on the date of mailing of an action under 35 U.S.C. § 132 if the appeal did not result in a decision by the BPAI. Patentees note that a notice of appeal was filed on February 5, 2008 and a non-final action under 35 U.S.C. § 132 was mailed on December 1, 2008, potentially generating 301 days of patent term to be excluded from this calculation. However, Applicants note that 291 days of patent term excluded for the notice of appeal overlaps with the 491 days of patent term excluded for continued examination (*i.e.*, from the date of filing of the notice of appeal, February 26, 2008, through the date of mailing of a on-final action under 35 U.S.C. § 132, December 1, 2008). Therefore, 20 days of patent term is excluded from this calculation due to the filing of a notice of appeal (*i.e.*, from the date of filing of the notice of appeal, February 5, 2008 through the day before the filing of the request for continued examination, February 25, 2008).

c) Three Year Delay Less Exclusions for Notice of Appeal and Continued Examination

In view of the exclusions for the notice of appeal and continued examination set forth above, Patentees have calculated that the period of the Three Year Delay under 37 CFR §1.702(b) is 345 days (856 days for the maximum Three Year Delay less 491 days excluded for continued examination and 20 days excluded for a notice of appeal).

(iv) Total Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), this period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the Four Month Delay (35 days), the 14 Month Delay (535 days) and the period of the Three Year Delay less the periods excluded for continued examination and appeal (345 days), or 915 days, to the extent that these periods of delay are not overlapping. As the period for the 14 Month Delay ended on April 25, 2005, prior to the period for the Four Month Delay (*i.e.*, June 28, 2008 through December 1, 2008) and prior to the first day of the period of the Three Year Delay (*i.e.*, February 25, 2007), Patentees submit that these periods are not overlapping.

B. "Patentee Delay" Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704(b), the period of adjustment shall be reduced for the period in excess of three months taken to reply to any Office notice or action making any rejection, objection, argument or other request, beginning on the day after the date that is three months after the date of mailing of the Office communication and ending on the date the reply was filed (hereinafter "Patentee Delay"). Accordingly, Patentees calculate that the period of adjustment described in section (A)(iv), above, is reduced by 212 days due to Patentee Delay, which is in agreement with the period calculated by the Office on the Patent Term Adjustment History (Appendix A).

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)

As set forth in 37 CFR §1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Patentee Delay. Therefore, Patentees submit that the correct patent term adjustment for the above-referenced

patent is **703 days**, which is the difference between the total period of examination delay (915 days) and Patentee Delay (212 days).

4. In accordance with 37 CFR §1.705(b)(2)(iii), Patentees submit that this patent is subject to a terminal disclaimer over U.S. Patent No. 7,326,696. However, Patentees note that the expiration date of U.S. Patent No. 7,326,696 is September 24, 2023, which is subsequent to the calculated expiration date of the above-identified patent, *i.e.*, June 2, 2023.

Dated: August 27, 2009

Respectfully submitted,

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